UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BAXTER HEALTHCARE CORPORATION, et al.,

Plaintiffs,

v.

FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, et al.,

Defendants.
_____/

No. C 07-1359 PJH

**ORDER RE MOTIONS FOR SUMMARY JUDGMENT**

The parties' motions for partial summary judgment came on for hearing before this court on September 2, 2009. Plaintiffs appeared by their counsel David Callahan, Garret A. Leach, Mary Elizabeth Zaug, Joseph Reagan, and Maureen K. Toohey. Defendants appeared by their counsel Michael E. Florey, Mathias Samuel, and John W. Kozak. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, the court hereby GRANTS plaintiffs' motion in part, DENIES it in part, and DEFERS ruling on it in part, and GRANTS defendants' motion is part and DENIES it in part.

**BACKGROUND**

The background of this case is as set forth in the February 10, 2009 Order Construing Claims ("Markman Order"). Briefly, plaintiffs Baxter Healthcare Corporation, Baxter International, Inc., and Baxter Healthcare SA (collectively, "Baxter"), and DEKA

Products Limited Partnership ("DEKA") filed this action on March 7, 2007, asserting nine patents against defendants Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, and Fresenius USA, Inc. (collectively, "Fresenius"). The patents involve or relate to systems and methods for performing peritoneal dialysis ("PD"), to assist patients suffering from end-stage renal disease.

Originally at issue were U.S. Patent No. 5,324,422 ("the '422 patent"); U.S. Patent No. 5,421,823 ("the '823 patent"); U.S. Patent No. 5,431,626 ("the '626 patent"); U.S. Patent No. 5,438,510 ("the '510 patent"); U.S. Patent No. 6,503,062 ("the '062 patent"); U.S. Patent No. 6,808,369 ("the '369 patent"); U.S. Patent No. 6,814,547 ("the '547 patent"); U.S. Patent No. 6,929,751 ("the '751 patent"); and U.S. Patent No. 7,083,719 ("the '719 patent").

On December 18, 2008, the court signed the parties' stipulation and proposed order staying the claims and defenses asserted as to the '751 and '719 patents. On May 28, 2009, the court signed the parties' stipulation and proposed order regarding the removal of functionality of Liberty Cycler, relating to the basis for Baxter/DEKA's assertion of claims of the '510, '062, and '369 patents. Thus, only the '823, '626, '422, and '547 patents are presently at issue.

In the present motions, Baxter/DEKA seek partial summary judgment as to certain invalidity contentions respecting all four of the patents at issue, and Fresenius seeks partial summary judgment as to the '823 patent and the '547 patent only. Fresenius also asserts that Baxter/DEKA's damages claim should be limited.

## DISCUSSION

A. Legal Standard

Summary judgment is appropriate when there is no genuine issue as to material facts and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. Material facts are those that might affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party. Id.

A party seeking summary judgment bears the initial burden of informing the court of the basis for its motion, and of identifying those portions of the pleadings and discovery responses that demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Where the moving party will have the burden of proof at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. Southern Calif. Gas. Co. v. City of Santa Ana, 336 F.3d 885, 888 (9th Cir. 2003).

On an issue where the nonmoving party will bear the burden of proof at trial, the moving party can prevail merely by pointing out to the district court that there is an absence of evidence to support the nonmoving party's case. Celotex, 477 U.S. at 324-25. If the moving party meets its initial burden, the opposing party must then set forth specific facts showing that there is some genuine issue for trial in order to defeat the motion. See Fed. R. Civ. P. 56(e); Anderson, 477 U.S. at 250.

A patent is entitled to a presumption of validity, and the burden of proof falls on the party seeking to establish the invalidity of a patent claim, who must overcome the presumption of validity in 35 U.S.C. § 282 by clear and convincing evidence. Metabolite Labs., Inc. v. Laboratory Corp. of America Holdings, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

B. Baxter/DEKA's Motion

Baxter/DEKA argue that they are entitled to summary judgment, first, as to Fresenius' invalidity contentions that conflict with the court's construction of certain of the disputed terms; and second, as to invalidity contentions for which Fresenius has submitted no expert opinions.

1. Motion as to invalidity contentions that conflict with claims construction

Baxter/DEKA argue that they are entitled to summary judgment as to certain invalidity contentions, which they claim conflict with the court's construction of certain disputed terms. Baxter/DEKA assert that the "pressure conveying element" and "pressure transferring element" limitations of the '626 patent are not indefinite, and that the asserted claims of the '823, '626, and '422 patents are not invalid for failure to enable or describe

actuation by a mechanical piston.

a. "pressure conveying element" and "pressure transferring element"

In its Final Invalidity Contentions, Fresenius alleges that under 35 U.S.C. § 112, ¶ 2, asserted Claims 34, 36-38, 41, 44, and 45 of the '626 patent are invalid because the term "pressure conveying element" is indefinite, and that asserted Claims 38, 40, 41, 44, and 45 of the '626 patent are invalid because the term "pressure transfer element" is indefinite. Fresenius contends further that the court's construction of "pressure conveying element" is indefinite because it defines the claimed element in terms of what it does, not what it is; and that "pressure conveying element" has no commonly accepted or understood meaning in the art, and a person of ordinary skill in the art would therefore not be able to determine the structural boundaries of the claimed "pressure conveying element."[1]

Section 112, ¶ 2 requires that the specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. Under this provision, "[t]he definiteness of a claim term depends on whether that term can be given any reasonable meaning." Datamize, LLC v. Plumbtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005). Thus, a claim is indefinite if a person of ordinary skill in the art would not understand its scope when reading the claim in light of the specification. See, e.g., Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249 (Fed. Cir. 2008).

Generally, indefiniteness is a question of law to be determined by the court. Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692 (Fed. Cir. 2001). However, the indefiniteness inquiry may involve underlying questions of fact. See BJ Servs. Co. v. Halliburton Energy Servs., Inc., 338 F.3d 1368, 1372 (Fed. Cir. 2003) ("Like enablement, definiteness, too, is amenable to resolution by the jury where the issues are factual in nature."). In particular, where evidence beyond the claims and the written description may be reviewed, factual issues may arise. See, e.g., Dow Chem. Co. v. NOVA Chems. Corp.

[1] The court was not asked to construe "pressure transfer element."

(Canada), 629 F.Supp. 2d 397, 402-04 (D. Del. 2009).

In the Markman Order, the court construed the disputed term "pressure conveying element" as used in asserted Claims 34, 38, 41, and 44 of the '626 patent as having a "plain and ordinary meaning" because the term involved "commonly understood words." Markman Order at 12. The court also found that the claims themselves explained what the "pressure conveying element" is used for – "conveying fluid pressure to the diaphragm to operate the pump chamber and valve." Id. The court noted particular pressure-conveying elements described in the specification, but concluded that the '626 patent does not suggest that "pressure conveying element" is limited to any particular embodiment, and that therefore "specific pressure conveying components cannot be read into the claim." Id.

Baxter/DEKA argue that because the court was able to construe this term, it cannot be indefinite under § 112, ¶ 2. They also note that Fresenius' recent invalidity contentions repeat the same arguments that Fresenius made in claim construction, which were rejected by the court. Finally, Baxer/DEKA assert that "pressure transfer element" is not indefinite under 35 U.S.C. § 112, ¶ 2, as the claim construction and validity analysis of this term "mirrors" the analysis the court undertook to construe "pressure conveying element."

Baxter/DEKA contend that because Fresenius' arguments for indefiniteness of the "pressure transfer element" limitation are identical to those it raises for the "pressure conveying element," the court should reject them for the same reason. They argue that although neither party found it necessary for the court to construe the term "pressure transfer element," the court previously addressed nearly identical issues in construing "pressure conveying element." Thus, according to Baxter/DEKA, for the same reason that "pressure conveying element" is not indefinite, the court should find that "pressure transfer element" is not indefinite.

Fresenius argues, however, that a person of ordinary skill would not be able to translate "pressure conveying element" (or the unconstrued "pressure transfer element") into a meaningfully precise claim scope. Fresenius claims that because "pressure conveying element" has no commonly accepted or understood meaning in the art, a person

of ordinary skill in the art would not be able to determine the structural boundaries of the claimed limitation, and thus would not be able to determine whether a device includes a structure covered by the claimed "pressure conveying element."

Fresenius also argues that the court's construction of "pressure conveying element" provides no definite claim scope beyond pure function (what it does, as opposed to what it is). Fresenius argues that under this construction, any structure under the sun that conveys pressure would be covered by Baxter/DEKA's asserted claims. Fresenius contends that this is exactly the sort of overbreadth that is inherent in open-ended functional claims, and which Congress wanted to preclude by enacting § 112, ¶ 6.

Similarly, Fresenius asserts, the limitation "pressure transfer element" is also indefinite, as the '626 patent specification does not define "pressure transfer element" and the phrase has no commonly accepted meaning in the art. Thus, Fresenius contends, the phrase is indefinite as it describes the claimed element only in terms of what it does, not what it is, with the same result as above.

Fresenius argues that the indefiniteness of "pressure conveying element" is further demonstrated in this case by the inability of Baxter/DEKA or their expert to differentiate the claimed "pressure conveying element" from the claimed "pressure transfer element." Fresenius points to Claims 38, 41, and 44 of the '626 patent, each of which recites "[a] system for performing peritoneal dialysis comprising: . . . . a pressure conveying element carried within the housing for conveying fluid pressure including a pressure transfer element . . . ." '626 patent, 43:59-61; id., 44:23-25; id., 44:56-58. Fresenius contends that the plain language of the claims dictates that there is a difference between "pressure conveying element" and "pressure transfer element."

As noted above, the parties did not request construction of "pressure transfer element." At the hearing on the present motion, the court asked whether Baxter/DEKA was requesting that the court construe "pressure transfer element," and counsel for Baxter/DEKA responded, "No." Nevertheless, counsel indicated that "[t]he analysis is similar to the analysis this Court went through for pressure conveying element," and

asserted that "all we're asking Your Honor to do is say, as a matter of law, sitting here at summary judgment, there isn't any argument Fresenius could present to the jury which would meet its clear and convincing burden of [proving that the claims are indefinite]." Reporter's Transcript, September 2, 2009 ("Tr.") at 6-7.

The court is at a loss as to how to resolve this dispute. Notwithstanding the assertion of counsel for Baxter/DEKA that the court should apply an analysis to the construction of "pressure transfer element" that is "similar" to the analysis it applied in construing "pressure conveying element," the fact remains that the parties did not brief the question of the proper construction of "pressure transfer element."

Accordingly, the court has determined to withdraw its prior construction of "pressure conveying element," and to allow further argument by the parties. The parties shall submit supplemental briefing regarding the construction of "pressure transfer element" and the construction of "pressure conveying element" (noting in particular that the claimed "pressure conveying element" is "carried within the housing for conveying fluid pressure including a pressure transfer element . . . ," '626 patent, 43:59-61; id., 23-25; id., 44:56-58); and also regarding the indefiniteness argument(s).

Baxter/DEKA's brief (not to exceed 10 pages) shall be filed no later than seven days from the date of this order; Fresenius' brief (not to exceed 10 pages) shall be filed no later than seven days thereafter; and any reply by Baxter/DEKA (not to exceed 10 pages) shall be filed seven days after Fresenius files its brief. The parties are encouraged to make their arguments as comprehensible as possible.

The court will consider the parties' arguments and issue a ruling on the papers. In addition, as soon as the construction issue and the issue(s) raised by the present motion are resolved, the parties will be given leave to withdraw their pretrial papers and update or replace them as appropriate.

b. asserted claims of the '823, '626, and '422 patents

In its Final Invalidity Contentions, Fresenius alleges that the asserted claims of the '823, '626, and '422 patents disclose only a PD system in which the pumping of the system

is accomplished pneumatically; that the patents do not disclose or teach incorporating a mechanical piston that actuates the diaphragm of a diaphragm pump for pumping the dialysis liquid; and that there is no teaching or hint as to how the purely pneumatic pumping system disclosed in the patents could be modified to include a mechanical piston that actuates the diaphragm of a diaphragm pump. For these reasons, Fresenius asserts, the asserted claims are invalid under 35 U.S.C. § 112, ¶ 1, for failure to satisfy the enablement and written description requirements.

In the present motion, Baxter/DEKA contend that the asserted claims of the '823, '626, and '422 patents are not invalid for failure to enable or describe actuation by a mechanical piston. They note that all three patents claim the use of fluid pressure, and argue that the enablement and written description requirements apply only to claimed inventions.

In its claims construction brief, Fresenius argued that the term "applying fluid pressure to the diaphragm to operate the pump chamber" in the '823 patent should be construed as "applying alternating positive and negative fluid pressure pulses to the diaphragm such that the diaphragm is flexed in and out and liquid moves through the pump chamber." The parties agreed as to the meaning of each of the words in the term, with the exception of "to operate." Fresenius contended that "to operate" had to be construed as requiring both positive and negative fluid pressure pulses.

In the Markman Order, the court found that "applying pressure through a gas or liquid to the diaphragm to operate the pump chamber" in the '823 patent means "applying pressure through a gas or liquid to the diaphragm to operate the pump chamber." See Markman Order at 4-7. The court found nothing in the specification indicating that the patentees intended to give any special meaning to the words "to operate," and that the claim language preceding and following "to operate" – "applying fluid pressure to the diaphragm" and "to either move dialysis solution fluid from the peritoneal cavity or more dialysis fluid into the peritoneal cavity" – clearly explained how the "operation" occurs and what it accomplishes. Id. at 7. The court concluded that "[t]he '823 patent claim language

is not limited to pneumatics, is not limited to alternating positive and negative fluid pressure pulses, and is not limited to flexing the diaphragm in and out." Id. at 6-7.

The '626 patent contains claim language that is nearly identical to the language in the '823 patent, cited above: "conveying fluid pressure . . . to the diaphragm to operate the pump chamber and valve . . . " Although the court was not asked to construe this term from the '626 patent, Baxter/DEKA argue here that the very similar claim language and nearly identical specifications require the same analysis and construction.

Finally, with regard to the '422 patent, the court construed the means-plus-function term "actuator means for operating the pumping mechanism," finding that the corresponding structure was the "piston element [the structure that forms the pump actuator], port and pump actuator components of the piston head assembly, and equivalents thereof." Markman Order at 7-11. Baxter/DEKA contend that there is no suggestion in this construction that the claims require mechanical actuation.

Title 35 § 112 describes what must be contained in the patent specification. Among other things, it must contain "a written description of the invention, and of the manner and process of making and using it . . . [such] as to enable any person of ordinary skill in the art to which it pertains . . . to make and use the same . . . ." 35 U.S.C. § 112 ¶ 1. The Federal Circuit has interpreted this statutory language as mandating two separate and independent requirements: an applicant must both describe the claimed invention adequately and enable its reproduction and use. See, e.g., Carnegie Mellon University v. Hoffmann-La Roche, Inc., 541 F.3d 1115, 1121 (Fed. Cir. 2008) (Section 112 ¶ 1 "requires a written description of the invention – a requirement separate and distinct from the enablement requirement"); see also Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).[2]

Section 112's "written description requirement" states that the "specification shall

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[2] The court notes, however, that the Federal Circuit is presently considering an appeal raising the question whether § 112, ¶ 1 contains a written description requirement separate from an enablement requirement; and if so, what the scope and purpose of the requirement is. See Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 332 Fed. Appx. 636, 2009 WL 2573004 (Fed. Cir., Aug. 21, 2009) (order vacating April 3, 2009, 560 F.3d 1366, opinion, reinstating appeal, and granting petition for rehearing en banc).

contain a written description of the invention." 35 U.S.C. § 112, ¶ 1. A patent need not describe every possible embodiment or potential infringing product to meet this requirement. SuperGuide Corp. v. DirecTV Enters., Inc., 358 F.3d 870, 880 (Fed. Cir. 2004). However, the specification "must describe an invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented what is claimed." Kao Corp. v. Unilever U.S., Inc., 441 F.3d 963, 967-68 (Fed. Cir. 2006).

Under § 112's "enablement" requirement, a patent's specification must describe the "manner and process of making and using [the invention], in such clear and concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use [the invention]." 35 U.S.C. § 112, ¶ 1. The enablement requirement "is often more indulgent than the written description requirement." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003). The specification need not enable every embodiment of a claim. Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009). Nor need the specification "explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without "'undue experimentation.'" Amgen, 314 F.3d at 3334 (citing Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, (Fed. Cir. 1997)).

Here, the parties make essentially the same arguments regarding both enablement and written description. Baxter/DEKA contend that the asserted claims of the '823, '626, and '422 patents are not invalid for failure to enable or describe actuation by a mechanical piston. Baxter/DEKA assert that the enabling and written description requirements apply to the claimed invention, which this court has already found (at least with regard to the '823 patent) to require "applying pressure through a gas or liquid to the diaphragm to operate the pump chamber." Markman Order at 4-11.

Baxter/DEKA argue that because the court already determined during claim construction that mechanical actuation is not part of the language of the properly construed, asserted claims of the '823, '626, and '422 patents, Fresenius' invalidity

contention runs counter to the court's Markman order. They assert that Fresenius is attempting to have the court re-construe the terms in Fresenius' favor. They note that during claim construction, Fresenius asserted that the claims preclude mechanical actuation – e.g., that the claims are limited to a purely pneumatic system – but that the court found (at least as to the asserted claims of the '823 patent) that "the claim language itself is not limited to pneumatics . . . ." Markman Order at 6.

Baxter/DEKA assert that the specifications of the '823, '626, and '422 patents meet both the enablement and the written description standard of 35 U.S.C. § 112, ¶ 1, because they enable a person of skill in the art to practice the claims and they describe the claims in sufficient detail as the court has construed them – namely the application of fluid pressure to operate the pump chamber. Baxter/DEKA argue that because the claims require fluid pressure actuation, their alleged silence as to mechanical actuation is not relevant and cannot be a basis for invalidity under § 112, ¶ 1. Thus, Baxter/DEKA assert, summary judgment is warranted on this issue.

In opposition, Fresenius denies that it has ever taken the position that the claims require mechanical actuation. Instead, it asserts, its position is simply that the claims are invalid because Baxter/DEKA have failed to enable or describe the claims in full. Fresenius argues that the fact that a mechanical pump is not required by the claims does not exempt the patentee from enabling and describing the full scope of the claims; and that there is a genuine issue of disputed fact as to whether a person of skill in the art would understand the '823, '626, and '422 patents to enable and describe the full scope of the claims as asserted by Baxter/DEKA.

Fresenius contends that there are, at a minimum, questions of fact as to whether a person skilled in the art, who read the '823 patent specification, would understand the inventors to have invented or enabled a pumping mechanism that combines a mechanical piston to actuate the diaphragm and pneumatics to merely adhere the diaphragm to the piston head. Fresenius asserts that the patents' specification provides absolutely no guidance to a person skilled in the art as to how they should practice the full scope of the

claims as asserted by Baxter/DEKA in this case.

Part of the problem here is that the parties are talking at cross-purposes. Baxter/DEKA seek a fairly broad ruling that the asserted claims of the '823, '626, and '422 patents meet the enablement and written description requirements, and enable a person of skill in the art to practice those claims.

Fresenius, on the other hand, appears to be arguing that its Liberty Cycler does not infringe the asserted claims of the '823, '626, and '422 patents because the claims are invalid for failing to enable and provide a written description of a method of performing PD in which mechanical actuation is assisted by pneumatics. Specifically, Fresenius alleges in its Final Invalidity Contentions that the asserted claims of the '626 patents do not enable or describe actuation by a mechanical piston, and that "to the extent that [the asserted claims] are deemed to cover any version of the Liberty Cycler, they are invalid under 25 U.S.C. § 112, ¶ 1, for lack of enablement and failure to meet the written description requirement."

While it asserts, in its opposition to the present motion, that the asserted claims of the '823, '626, and '422 patents "[c]learly . . . do not require mechanical actuation," Fresenius also argues that Baxter/DEKA "have asserted an extremely broad claim scope in order to accuse the Liberty Cycler." In support, Fresenius cites asserted claim 1 of the '823 patent, which claims a method for performing PD, comprising the steps of "establishing flow communication with the patient's peritoneal cavity through a pumping mechanism . . . " and "emulating a selected gravity flow condition by applying fluid pressure to the diaphragm to operate the pump chamber to either move dialysis solution fluid from the peritoneal cavity or move dialysis solution into the peritoneal cavity." '823 patent, 38:21-31.

Fresenius then argues, as part of a larger discussion of infringement (not at issue here) that Baxter/DEKA's infringement theory is that the Liberty Cycler, which uses a mechanical pump, practices the asserted claims for brief instances only during the drain cycle and during the pistons' instroke.

At the hearing, counsel for Baxter/DEKA stated that "[t]he claims do not require mechanical actuation." Tr. at 22. In response, counsel for Fresenius agreed that "none of

these claims require mechanical actuation," adding that "[t]hat is not the basis of our lack of written description and lack of enablement defenses." Id. at 23-24; see also id. at 24-25. However, to the extent that the court understands Fresenius' arguments, it appears that that is exactly what Fresenius is asserting in its Final Invalidity Contentions and in its opposition to the present motion.

The Federal Circuit has clearly indicated that it is the full scope of the claimed invention that must be enabled. See, e.g., Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008). Similarly, the "written description" requirement mandates that the specification "describe the claimed invention in 'full, clear, concise, and exact terms.'" Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (quoting 35 U.S.C. § 112, ¶ 1) (emphasis added); see also Amgen, 314 F.3d at 1333 ("under our precedent the patentee need only describe the invention as claimed, and need not describe an unclaimed method of making the claimed product").

It is the ruling of the court that if the asserted claims do not require mechanical actuation – and the parties have agreed that there is no such requirement – the enablement and written description requirements (which apply only to the "claimed" invention) cannot impose on the patent holders the necessity of enabling or describing mechanical actuation. Accordingly, this question cannot be presented to the jury.

However, as the determination of the larger question whether the written description and enablement requirements are satisfied involves fact-based inquiries, see Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1378 (Fed. Cir. 2009) (enablement); Carnegie Mellon University v. Hoffmann-La Roche, Inc., 541 F.3d 1115, 1122 (Fed. Cir. 2008) (written description); and as this issue is not before the court, the court DENIES Baxter/DEKA's motion insofar as they seek a ruling that all asserted claims of the '823, '626, and '422 patents meet the enablement and written description requirements.

That is, to the extent that any dispute remains regarding whether the '823, 626, and '422 patents meet the enablement and written description requirements, and that dispute does not involve the question whether the asserted claims require mechanical actuation,

such dispute may be given to the jury.

2. Motion as to invalidity contentions for which Fresenius submitted no expert opinion

Baxter/DEKA argue that they are entitled to summary judgment as to certain invalidity contentions for which Fresenius has submitted no expert opinion. Baxter/DEKA assert that in order to overcome the presumption of validity of the patents-in-suit by clear and convincing evidence, Fresenius must provide expert testimony regarding its prior-art-based contentions, as discussed below.

Baxter/DEKA identify three such contentions – (1) that claim 12 of the '547 patent is anticipated or rendered obvious by certain prior art references; (2) that the '823, '626, and '422 patents are anticipated by certain prior art references; and (3) that the asserted claims of the '823 patent are rendered obvious by certain prior art references.

Baxter/DEKA assert, with regard to each of these, that Fresenius' expert(s) failed to find any invalidating references or combinations, with the exception of the on-sale bar as to (2), and the combination of the Bergstrom Article, the '215 patent, and the '515 patent as to (3). Baxter/DEKA contend that they are entitled to summary judgment on invalidity contentions for which Fresenius cannot meet its burden of proof.

In opposition, Fresenius asserts that it should not be precluded at this stage from arguing theories properly set forth in its invalidity contentions, and that it should be permitted to present evidence at trial to support all of its invalidity contentions. Fresenius notes that the parties have collectively presented expert reports from, and have taken the depositions of, at least thirteen technical expert witnesses, and argues that if even half of these experts testify at trial, the jury will have more than ample guidance in understanding the technology at issue.

The motion is DENIED. This dispute raises an evidence preclusion issue, not a summary judgment issue. Fresenius should be advised, however, that it will likely be precluded from presenting expert testimony regarding prior art if such testimony reflects opinions that were not previously disclosed, and that it will also likely be precluded from

presenting prior art to the jury and, based solely on arguments of counsel, asserting that certain claims are anticipated or rendered obvious.

C. Fresenius' Motion

Fresenius argues that the asserted claims of the '823 patent are invalid because of a statutory on-sale bar; that claim 12 of the '547 patent is indefinite and therefore invalid; and that Baxter/DEKA's enhanced damages claim should be limited to a maximum of treble the compensatory damages (if any) from Fresenius' pre-suit conduct.

1. Motion as to invalidity of asserted claims of '823 patent because of statutory on-sale bar

Fresenius contends that the asserted claims of the '823 patent are invalid because the invention of the '823 patent was reduced to practice and was "ready for patenting" as of the Fall of 1989, but DEKA waited well over three years before it filed the application that resulted in the '823 patent. Fresenius also asserts that Baxter filed a pre-market notification in June 1992 advising the Food and Drug Administration that the Personal Cycler System was safe and effective, and that Baxter intended to market the device. However, the actual '823 patent application was not filed until March 3, 1993.

Section 102 of the Patent Act gives inventors a "grace period" of one year following commencement of commercial activity to file a patent application. 35 U.S.C. § 102(b) ("A person shall be entitled to a patent unless the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States."). Any attempt to commercialize the patented invention more than one year prior to filing the patent application creates an "on-sale bar" that invalidates a subsequently-issued patent. Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1368 (Fed. Cir. 2007).

The on-sale bar is intended, in part, to prevent inventors from exploiting the commercial value of their inventions while deferring the start of the statutory term of patent protection. Ferag AG v. Quipp, Inc., 45 F.3d 1562, 1566 (Fed. Cir. 1995). This rule applies when two conditions are satisfied: the product embodying the asserted claims must be the subject of a commercial offer for sale; and the invention must be ready for patenting. Pfaff

v. Wells Elecs., Inc., 525 U.S. 55, 67 (1998).

The question whether an invention is the subject of a commercial offer is a matter of Federal Circuit law, analyzed under the law of contracts as generally understood. Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1047 (Fed. Cir. 2001). To prove that an invention was the subject of a commercial sale, a defendant must demonstrate by clear and convincing evidence that there was a definite sale or offer to sell more than one year prior to the application for the patent, and that the subject matter of the offer to sell fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art. STX, LLC v. Brine, Inc., 211 F.3d 588, 590 (Fed. Cir. 2000).

The "ready for patenting" requirement may be satisfied by proof of reduction to practice before the critical date, or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. Pfaff, 525 U.S. at 67-68. Proof of "reduction to practice" generally provides the best evidence that invention is complete, although one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice. Id. at 66.

Fresenius asserts that in this case, the invention of the '823 patent was reduced to practice and ready for patenting as of the Fall of 1989, and that between that time and the time the patent application was filed in March 1993, DEKA commercially exploited its invention, garnering millions of dollars in fees from Baxter to incorporate the invention into a commercial product.

DEKA was founded by Dean Kamen ("Kamen"), one of the named inventors on the '823 patent. DEKA and Kamen have designed medical products for Baxter since the early 1980s. Fresenius contends that Baxter approached Kamen in 1987 or 1988 to ask him for help with problems Baxter was experiencing with its PAC-X PD cycler, and that Kamen suggested that instead of fixing the PAC-X, he could design and build a new PD cycler for Baxter.

Citing Baxter/DEKA's responses to interrogatories, Fresenius claims that Kamen

and his colleagues at DEKA conceived of the pneumatic pumping technique claimed in the '823 patent by the Spring of 1988, and had reduced it to practice by the Fall of 1989. Fresenius notes that DEKA has admitted the reduction to practice of Claims 1-21, 23-25, 27-29, and 31 of the '823 patent occurred at least as early as Fall 1989, and the reduction to practice of Claims 22, 26, and 30 occurred at least as early as March 3, 1993. Thus, Fresenius contends, of the '823 patent claims asserted by Baxter/DEKA – Claims 1, 4, 5, 10, 13, and 14 – all were reduced to practice as early as Fall 1989.

In May 1990, Baxter and DEKA entered into a Global Agreement Concerning New Product Development for Dialysis ("the Global Agreement"), which set forth the terms and conditions under which DEKA would "attempt to develop [n]ew [p]roducts for Baxter," during the period from the effective date of the agreement until January 4, 1993. Fresenius claims that by August 1991, Baxter and DEKA had developed the "Personal Cycler System," and decided to manufacture it and bring it to market.

On August 5, 1991, DEKA and Baxter entered into a Personal Cycler Manufacturing and License Agreement ("PCMLA"). The PCMLA stated that "Deka has developed with Baxter a peritoneal dialysis system known as the 'Personal Cycler System,'" and that "[t]he Personal Cycler System includes . . . [listing components]," and that the parties agreed to work together "in the performance of certain pre-manufacturing services and initial manufacturing of" hardware and disposable components of the Personal Cycler System. They anticipated that "commercial introduction of the Personal Cycler System" would occur "on or about August 1, 1992."

Fresenius asserts that there is no doubt that the Personal Cycler described in the PCMLA embodies the asserted claims of the '823 patent, as Baxter/DEKA have consistently taken the position that the Baxter HomeChoice™ cycler embodies all the asserted claims of the '823 patent, and that the "Personal Cycler System" was the name used for the HomeChoice™ product before Baxter selected the trademarked name. Thus, based on the above-quoted statement in the PCMLA – that "Deka has developed with Baxter a peritoneal dialysis system known as the 'Personal Cycler System'" – Fresenius

contends that the invention was reduced to practice and ready for patenting as of the date the parties entered into the PCMLA.

Baxter/DEKA argue, however, that the cited statement must be read in the context of the entire agreement, which shows that the development of the Personal Cycler was not yet complete as of the time the parties entered into the PCMLA. They note that Article 1.2 expressly states that the parties did not have a "final product" and that Article 3.2 indicates that product specifications were not complete (let alone "finalized and formally accepted").

Fresenius also contends that the PCMLA includes an offer by DEKA to sell the Personal Cycler System to Baxter, and that it requires DEKA to supply the Personal Cycler System to Baxter in exchange for money. Fresenius claims that the PCMLA is a "requirements contract," in which DEKA agreed to supply Baxter with its "requirements" of the Personal Cycler product, and so does not state a precise quantity term; and which states that the "purchase price" will be the amount actually charged by DEKA's vendors to manufacture the product, plus "additional compensation" paid to DEKA for its manufacturing services

Thus, Fresenius asserts, the on-sale bar applies because DEKA and Baxter signed the PCMLA more than one year before the patent application date of March 3, 1993. Fresenius argues that had DEKA filed within a year of the date it admits the invention was "ready for patenting," the '823 patent would have expired near the end of 2010. As it is, however, the '823 patent is not set to expire until March of 2013.

In opposition, Baxter/DEKA assert that they did not violate the on-sale bar. They argue that it was only after they had developed the system and filed the application leading to the '823 patent, that they first tested the Personal Cycler on a patient, secured FDA approval, and commercially launched the HomeChoice™ PD system.

According to the chronology provided by Baxter/DEKA, a period of "research and development" extended from January 5, 1990 (the date of the Global Agreement) through August 5, 1991 (the date of the PCMLA), and up to March 3, 1992 ("the critical date" – one year prior to the filing of the patent application). Then starting on March 6, 1992, and

running to July 7, 1994 (the commercial "launch date" of the HomeChoice™ system), Baxter and DEKA engaged in "manufacturing and commercialization."

Baxter/DEKA claim that the first agreement that provided for the actual manufacture and sale of the Personal Cyclers to Baxter did not arise until after the "critical date." They assert that under the May 1992 Vendor-Produced Finished Goods Purchase Agreement ("Vendor Agreement"), Nova Biomedical agreed to manufacture and sell Personal Cyclers to Baxter upon formal acceptance and approval of a final specification, although various terms were left open for later agreement. They contend that DEKA managed Nova Biomedical's performance under the Vendor Agreement, pursuant to the PCMLA. They assert, however, that nothing in the PCMLA or the Vendor Agreement required DEKA to make, sell, or offer for sale any PD machine to Baxter.

According to Baxter/DEKA, they continued to "refine" and change the Personal Cycler after signing the Vendor Agreement. On March 3, 1993, while these changes were still ongoing, DEKA filed the application that led to the '823 patent – which Baxter/DEKA assert was three days before the earliest possible trigger of the on-sale bar. They contend that it was only after this that they first tested the Personal Cycler on a patient, finally performing peritoneal dialysis.

Baxter/DEKA contend that in May 1993, Baxter began extensive patient evaluations in a Test Market Evaluation ("TME"), designed to test the HomeChoice™ system in the hands of users in the actual environment in which the product would be used. During and after the TME, Baxter/DEKA worked on a "significant maturation of the product" and on improvement in the reliability and performance of the alarms.

In November 1993, Nova Biomedical planned to perform a third of three pre-production runs, incorporating further design changes. Baxter/DEKA assert that it was only after this third pre-production build that the Personal Cycler Systems were to be considered "Normal Production machines." Baxter received FDA approval for the HomeChoice™ PD device on March 4, 1994, and commercially launched the HomeChoice™ in July 1994 – nearly three years after the PCMLA's effective date.

Having considered the parties' arguments, the court finds that the motion must be DENIED. Fresenius has not established that the asserted claims of the '823 patent are invalid because of a statutory on-sale bar. Fresenius' position is that the PCMLA obligates DEKA to supply the Personal Cycler System to Baxter, and obligates Baxter to pay for machines and disposables supplied by DEKA; and that Article 8 of the PCMLA shows that DEKA – the patent owner – undertook a legal obligation to sell the Personal Cycler System to Baxter.

The court has read the PCMLA carefully, however, and does not agree with the interpretation urged by Fresenius. The PCMLA is a contract for services and a patent license, rather than an enforceable commercial "supply" agreement or a "requirements" contract, as it requires DEKA to provide manufacturing administration services and technical assistance to an eventual third-party manufacturer, and does not provide for the transfer of title in any Personal Cycler from DEKA to Baxter. Neither the contemplation of future commercialization of a product nor the granting of a license to an invention in itself triggers the on-sale bar. See In re Kollar, 286 F.3d 1326, 1330-31 (Fed. Cir. 2002)).

The face of the PCMLA reflects that the intent of the parties was for Baxter to have the components manufactured by the vendors, and then assembled for Baxter, which would then own the finished product. PCMLA, Arts. 4, 5, 6. DEKA's role would be limited to providing certain "pre-manufacturing services," and to managing the third-party manufacturers who contracted to sell the components to Baxter at some future time. Id., Arts. 4, 5, 8.

DEKA agreed to "advise and consult with Baxter," to "negotiate Vendor contracts," to "schedule and coordinate the work of all Vendors;" to "keep Baxter and Vendors informed as to Baxter's production requirements and delivery schedules," and to oversee the Vendors who would actually manufacture and sell the Personal Cycler; and that Baxter would "remit payment directly to Vendor(s), with written confirmation of payment to Deka." Id., Art. 5.

There is no support in the PCMLA for Fresenius' suggestion that DEKA was

authorized to add anything on top of those vendor invoices for itself. Article 5.3 of the PCMLA, "Vendor Payments," provides that "[i]n the event Deka has made a payment on Baxter's account, Deka will be reimbursed by Baxter in accordance with the Application for Payment." Thus, DEKA was entitled to recover its direct costs from Baxter, and there is no indication that the invoices represent anything other than requests for compensation for direct costs or for manufacturing services.

Pursuant to the PCMLA, DEKA was compensated for supervising the Vendors, for facilitating the provision of hardware and disposables to Baxter by the vendors, and for implementing improvements in manufacturing and quality assurance, among other things, id., Art. 10.2, as well as for its research and development services, per the Global Agreement, but DEKA did not "own" a product that it was then selling to Baxter.

Because Baxter did not seek summary judgment as to this affirmative defense, the court cannot rule for Baxter on the issue of the on-sale bar. However, Fresenius has not presented evidence sufficient to raise a triable issue as to whether the Personal Cycler was "on sale" more than a year before the patent application was filed. In order to present this question to the jury, Fresenius will need evidence other than the evidence it relied on in this motion.

2. Motion as to invalidity of Claim 12 of the '547 patent

Fresenius argues that Claim 12 of the '547 patent is indefinite and therefore invalid. Claim 12 of the '547 patent is directed to a pump connected to a vacuum source, and claims

> A pump connected to at least one vacuum source for use in a system for providing dialysis treatment, the pump comprising:
>
> a first chamber wall;
>
> a second chamber wall, the second chamber wall defining an aperture;
>
> **first and second fluid receiving membranes disposed between the first and second chamber walls, the at least one vacuum source operable to apply a vacuum between the membrane and the walls;**
>
> a piston, at least a portion of which moves through the aperture, the piston including a piston head having an external shape substantially similar to a

> mating internal shape of the first chamber wall, the piston in operation contacting **one of the membranes**;
>
> a dialysis fluid opening enabling dialysis fluid to be pulled in **between the first and second membranes** upon movement of the piston.

'547 patent, 58:27-45 (emphasis added).

Fresenius asserts that the claim is indefinite because the claimed invention requires two membranes ("first and second fluid receiving membranes"), and the language in the claim fails to identify which of the two membranes the claim is referencing in the phrase "apply a vacuum between the membrane and the walls." Fresenius cites to the Manual of Patent Examining Procedure ("MPEP") for the following proposition: "A claim is indefinite when it contains words or phrases whose meaning is unclear. . . . Similarly, if two different levers are recited earlier in the claim, the recitation of 'said lever' in the same or subsequent claim would be unclear where it is uncertain which of the two levers was intended." MPEP § 2173.05(e).

Fresenius contends that the specification of the '547 patent fails to resolve this ambiguity, and in fact confirms that the claim is indefinite. Fresenius asserts that the "first and second fluid receiving membranes" recited in Claim 12 are the "upper" and "lower" membranes 162 and 164 illustrated in Fig. 17A. As noted above, Claim 12 requires that the vacuum be applied between "the membrane" and the walls. Fresenius argues, however, that specification does not clarify which of the two membranes – the upper membrane or the lower membrane – is being referenced in the phrase "the . . . vacuum source operable to apply a vacuum between the membrane and the walls."

Fresenius asserts further that the specification shows that vacuum is applied to these two different membranes through two different pathways – the vacuum source exerts a vacuum on the upper membrane through aperture or port 222, and on the lower membrane through an aperture 221 defined by housing 223, and through the port or aperture 220. See '547 patent, 33:20-26. Thus, Fresenius argues, a person of skill in the art would be unable to determine which "membrane" the vacuum is applied to, and therefore would be unable to ascertain the scope of the claim. For this reason, Fresenius

contends, the claim is indefinite.

Fresenius adds that the other references to "membranes" do not resolve the issue. Claim 12 refers to "the piston" contacting "one of" the two membranes, id., 58:40-41; and also recites that upon movement of the piston, dialysis fluid is "pulled in between the first and second membranes," id., 58:42-43 However, Fresenius argues, these elements do not help clarify the issue.

In opposition, Baxter/DEKA make three main arguments – that the patent examiner allowed Claim 12 with the addition of the limitation Fresenius now attacks; that the meaning of the claim term "the membrane" is clear when read in light of the entirety of Claim 12 and the specification; and that persons of ordinary skill in the art would understand that "the membrane" is the second fluid-receiving membrane.

First, Baxter/DEKA assert that the patent examiner initially rejected pending Claim 12 under § 112, and that Baxter then added this exact limitation to Claim 12. The patent examiner subsequently allowed Claim 12 with the addition of the limitation Fresenius now attacks, and issued the Notice of Allowance.

Baxter/DEKA argue that because the addition of the limitation "the at least one vacuum source operable to apply a vacuum between the membrane and the walls" convinced the patent examiner that Claim 12 met § 112's requirements and was allowable, the court should presume that the examiner performed his duty and allowed a valid claim. Citing Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308 (Fed. Cir. 1999), they contend that "[t]he presumption of validity under 35 U.S.C. § 282 carries with it a presumption that the Examiner did his duty and knew what claims he was allowing." Id. at 1323.

Second, Baxter/DEKA argue that the meaning of the claim term "the membrane" is clear when read in light of the entirety of Claim 12 and the specification. They note that in citing the quoted excerpt from MPEP § 2173.05(e), Fresenius has omitted a key portion of the text. The full statement is as follows (underlined portion was omitted by Fresenius).

> A claim is indefinite when it contains words or phrases whose meaning is unclear. . . Similarly, if two different levers are recited earlier in the claim, the

> recitation of "said lever" in the same or subsequent claim would be unclear where it is uncertain which of the two levers was intended . . . . Obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite.

Claim 12 states that "the piston in operation contact[s] one of the membranes," and Baxter/DEKA assert that the only one of the two membranes that is capable of contacting the piston is the one located closest to the piston head and the second chamber wall. They contend that the specification provides further guidance as it discloses that a vacuum is used to couple the second fluid receiving membrane to the piston head. See '547 patent, 5:7-9; id., 33:27-29.

Baxter/DEKA contend that the claim and the specification make clear that the piston is moving through the aperture in the second chamber wall, and that the second fluid receiving membrane is closest to the piston head. Thus, they argue, it is the second fluid receiving membrane that is referred to in Claim 12 as "the membrane."

The court finds that the motion must be DENIED. To show a claim indefinite, the accused infringer must "show by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." Halliburton, 514 F.3d at 1244. Here, Fresenius has not established by clear and convincing evidence that a skilled artisan would not understand that when the claim requires a vacuum applied between "the membrane" and the walls, the membrane referenced is the second fluid receiving membrane.

Claim 12 recites "first and second fluid receiving membranes disposed between first and second chamber walls," with the second chamber wall "defin[ing] an aperture." In addition, a piston, "at least a portion of which moves through the aperture, in operation contact[s] one of the membranes." Only one piston is claimed, and that piston moves through the only claimed aperture (which is located in the second chamber wall). Since both fluid receiving membranes are disposed between the two chamber walls, one of the membranes must be closer to the first chamber wall, while the other membrane must be

closer to the second chamber wall.

When the piston moves through the aperture, the membrane that it contacts must be the second fluid receiving membrane – the one that is closest to the second chamber wall – as that is the chamber wall that contains the aperture through which the piston moves. When the piston moves, dialysis fluid is pulled in between the first and second membranes. Thus, the "vacuum source operable to apply a vacuum between the membrane and the walls" refers to applying a vacuum between the second membrane, or the membrane closest to the piston head, and the walls.

Again, as with the issue of the on-sale bar, Baxter did not seek summary judgment as to this affirmative defense, and the court therefore cannot rule for Baxter on the question whether Claim 12 is valid. However, Fresenius has not presented evidence sufficient to raise a triable issue as to this defense. In order to present this question to the jury, Fresenius will need evidence other than the evidence it relied on in this motion.

3. Motion re limitation of damages

Fresenius argues that Baxter/DEKA's enhanced damages claim should be limited to a maximum of treble the compensatory damages (if any) from Fresenius' pre-suit conduct. Fresenius claims that the remedy that was available to Baxter/DEKA for any alleged willful, post-litigation conduct collapsed when Baxter/DEKA failed to move for a preliminary injunction at the inception of the case in March 2007, or when the allegedly infringing product was launched over a year and a half later, or at any time during the subsequent course of this litigation.

In opposition, Baxter/DEKA argue that Fresenius' motion to limit enhanced damages is both premature and legally unfounded. They contend that whether and to what extent they are entitled to enhanced damages is for the court to decide after the jury has heard all the evidence at trial and has decided that Fresenius' infringement was willful. In addition, Baxter/DEKA argue, to the extent that Fresenius is attempting to lay the groundwork for a motion in limine to limit the scope of admissible evidence to only pre-filing conduct, such limitation has no legal basis.

The motion is GRANTED. An award of enhanced damages in a patent infringement suit requires a showing of willful infringement. In re Seagate Tech., LLC, 497 F.3d 1360, 1368-74 (Fed. Cir. 2007); see also Jurgens v. CBK, Ltd., 80 F.3d 1566, 1570 (Fed. Cir. 1996) (bad faith infringement, which is a type of willful infringement, is required for enhanced damages).

In Seagate, the Federal Circuit stated that "in ordinary circumstances, willfulness will depend on an infringer's prelitigation conduct." Id., 497 F.3d at 1374. "By contrast, when an accused infringer's post-filing conduct is reckless, a patentee can move for a preliminary injunction, which generally provides an adequate remedy for combating post-filing willful infringement." Id. Moreover, the court observed, a patentee who does not attempt to stop an accused infringer's activities by seeking a preliminary injunction "should not be allowed to accrue enhanced damages based solely on the infringer's post-filing conduct." Id.

The court is persuaded by the reasoning in Seagate. As Baxter/DEKA did not seek injunctive relief to stop the alleged infringement, the court finds that they should not be entitled to seek enhanced damages for any post-filing infringement.

**CONCLUSION**

In accordance with the foregoing, plaintiffs' motion is GRANTED in part and DENIED in part, and the ruling is DEFERRED in part. Defendants' motion is GRANTED in part and DENIED in part.

Baxter/DEKA's motion to strike portions of Fresenius' reply in support of its motion for summary judgment, or in the alternative, to file a sur-reply, is DENIED, as Fresenius states in its response that it is not relying on the exhibits at issue as a basis for its motion.

**IT IS SO ORDERED.**

Dated: February 19, 2010

PHYLLIS J. HAMILTON
United States District Judge